Development and Validation of RP-HPLC Method & Dissolution Profiling of Tianeptine Sodium in its Pharmaceutical Dosage Form

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ABSTRACT

The purpose of this work is to develop a sensitive, selective, and validated RP-HPLC assay of Tianeptine Sodium in bulk drug and tablet form. Tianeptine Sodium was analyzed on INERTSIL ODS C18 column using isocratic elution with acetonitrile and water (pH 3) in ratio of 55:45. The mobile phase at a flow rate of 1.0 ml/min, Injection volume 10 µl and wavelength of detection was kept at 220 nm. The retention time for Tianeptine Sodium was 3.783 min. The linearity of the proposed method was investigated in the range of 10-80 µg/ml. Correlation coefficient was 0.9997, the limit of detection and limit of quantification was 0.3214 µg/ml and 0.9740 µg/ml respectively. Proposed methods were validated as per ICH guidelines for linearity, accuracy, precision, specificity and robustness for estimation of Tianeptine Sodium in commercially available tablet dosage form and results were found to be satisfactory. Dissolution profiling of Tianeptine Sodium tablets were done and their f1 & f2 were calculated and were obtained within range which suggested that these tablets were

comparable. Thus the developed and validated RP-HPLC method can be used successfully for marketed formulations.

Key words: Tianeptine Sodium, RP-HPLC method, Validation and Dissolution Profiling.